

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS\_\_\_\_\_  
SMITH & NEPHEW, INC., Plaintiff

v.

\_\_\_\_\_  
INTERLACE MEDICAL, INC., and  
HOLOGIC, INC., Defendants  
\_\_\_\_\_

CIVIL ACTION NO. 10-cv-10951-RWZ

**SMITH & NEPHEW, INC.'S OPPOSITION TO DEFENDANTS' EMERGENCY  
MOTION TO "STRIKE" PORTIONS OF PLAINTIFF'S EXPERT REPORT  
REGARDING INFRINGEMENT AND REQUEST FOR ORAL ARGUMENT**

To paraphrase a famous quote, Hologic protests too much. Apparently, Hologic does not believe it can succeed at trial, so it has resorted to fabricating procedural deficiencies in Smith & Nephew's disclosures: First, in Smith & Nephew's infringement contentions, and now in Smith & Nephew's Rule 26 expert disclosures. In doing so, Hologic has mischaracterized Smith & Nephew's infringement theory to this Court on multiple occasions, all the while preparing its own non-infringement defenses based on what, as it knows very well, are Smith & Nephew's actual infringement theories.

This abuse of procedure, including the excessive cost that Smith & Nephew has incurred in response to it, should not be entertained any further. Hologic's newest effort to preempt the substantive adjudication of Smith & Nephew's infringement claims goes too far. Smith & Nephew is entitled to present its infringement theories for adjudication in this matter at summary judgment and/or at trial, but the overly broad relief requested by Hologic would effectively preclude Smith & Nephew from presenting expert testimony on *any* of the Asserted Claims. That Hologic disagrees with those theories is not a sufficient reason to preclude Smith & Nephew from making its case.

Hologic's motion should be denied for at least three reasons, as set forth in further detail below:

- Hologic fails to identify a single procedural deficiency pursuant to Fed. R. Civ. P. 26 or a single evidentiary deficiency pursuant to *Daubert v. Merrill Dow Pharms.* On this basis alone, Hologic's motion should be denied.
- Smith & Nephew's Expert Report on Infringement ("Expert Report") and the theories set forth therein are consistent with this Court's claim constructions, the August 31<sup>st</sup> Order, and the Amended Final Infringement Contentions.
- Hologic seeks to preclude expert testimony on a claim term ("cutting member") that appears in claim elements beyond the "attached" element that has been the focus of Hologic's prior challenges to Smith & Nephew's disclosures. Hologic *has never contested whether the Accused Device meets additional claim elements on which Hologic now apparently asks this Court to preclude expert testimony*, yet it makes no such distinction in its request for relief.

Finally, Smith & Nephew opposes Hologic's request that this Court vacate the remaining deadlines in the Scheduling Order in this case until Hologic's motion has been resolved. Every day that Hologic manufactures, sells, and/or offers to sell the Accused Device damages Smith & Nephew's good will and position as an innovator in the marketplace. Thus, Smith & Nephew requests that the Scheduling Order remain in place, with the following exceptions.

Since the filing of Hologic's Motion to Strike on October 25th, the Parties have agreed, in the event that this Court does *not* vacate the remaining deadlines in the Scheduling Order as requested by Hologic, to the following extended deadlines solely related to the disclosure of expert reports on issues of liability:

Deadline for rebuttal expert reports (validity and non-infringement): Nov. 14, 2011;

Deadline for Hologic's sur-rebuttal report (secondary considerations: Nov. 21, 2011); and

Last day to complete expert depositions ((in)validity/(non)infringement): Dec. 9, 2011.<sup>1</sup>

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<sup>1</sup> For clarity, in agreeing to these proposed extended dates, Smith & Nephew understands that Hologic has not withdrawn its request to vacate the Scheduling Order until resolution of Hologic's motion to "strike."

**I. SMITH & NEPHEW’S EXPERT REPORT COMPLIES WITH THE REQUIREMENTS OF RULE 26, AND HOLOGIC DOES NOT EVEN ATTEMPT TO SUGGEST OTHERWISE.**

Hologic does not argue that the Expert Report fails to meet the procedural requirements for expert disclosures pursuant to Federal Rule of Civil Procedure 26(a)(2)(B). That is because the Expert Report indisputably complies with those requirements, including (i) a complete statement of all opinions Dr. Hogan will express and the basis and reasons for them; (ii) the facts or data considered by Dr. Hogan, particularly the Accused Device itself; (iii) static drawings of the Accused Device, as well as critical features of the embodiment depicted in the drawings of the ’459 Patent; (iv) Dr. Hogan’s qualifications, including a list of publications authored in the previous 10 years; (v) a list of all other cases in which, during the previous 4 years, Dr. Hogan testified as an expert at trial or by deposition; and (vi) a statement of the compensation to be paid for his work on the case. *Fed. R. Civ. P. 26(a)(2)(B)*.

Instead, without a single legal cite to a relevant rule or case, Hologic seeks to “strike” certain portions of the Expert Report, apparently in an attempt to preclude expert testimony on those portions of the Expert Report. Yet a motion to “strike” – made in a vacuum with no legal analysis and, notably, when no evidence or testimony has yet been submitted to the Court – is not an appropriate vehicle to preclude the admission of expert testimony. Rather, the Supreme Court has specifically addressed the admissibility of expert testimony pursuant to the Federal Rules of Evidence, and stated that, when “[f]aced with a proffer of expert scientific testimony, ... the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a factual issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts at issue.” *Daubert v. Merrill Dow Pharms.*,

509 U.S. 579, 592-93 (1993). The inquiry must be a flexible one, and “its overarching subject is the scientific validity – and thus the evidentiary relevance and reliability – of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.” *Id.* at 595.

Hologic fails to identify a single way in which the testimony it seeks to preclude is not relevant or scientifically valid. In fact, Hologic does not question the evidentiary relevance or reliability of Dr. Hogan’s anticipated testimony regarding the infringement of the Accused Device at all. That is because there is no such question. Dr. Hogan’s experience in the relevant art is squarely on point with the issues presented in this litigation. Further, his review and analysis of the Accused Device and his conclusions that the Accused Device infringe the ’459 Patent either literally or pursuant to the doctrine of equivalents are not based upon questionable or radical methodologies or techniques.

Because the Expert Report meets the requirements of Rule 26(a)(2)(B), and because there is no valid concern about the admissibility of Dr. Hogan’s expert testimony at trial pursuant to *Daubert*, Hologic’s motion should be denied.

## **II. THE EXPERT REPORT COMPLIES WITH THIS COURT’S CLAIM CONSTRUCTIONS AND THE AUGUST 31<sup>ST</sup> ORDER, AND IS CONSISTENT WITH SMITH & NEPHEW’S AMENDED INFRINGEMENT CONTENTIONS.**

Hologic’s primary complaint with Smith & Nephew’s expert report is the same as its complaint about Smith & Nephew’s amended contentions, the subject of Hologic’s other pending motion to “strike”: that Smith & Nephew’s infringement theories “are based on” Smith & Nephew’s original June 2, 2011 Final Infringement Contentions, and/or that the theories disclosed in the Expert Report somehow violate the “gravamen” of the August 31<sup>st</sup> Order.

First, neither the Expert Report nor the opinions disclosed therein are “based” on disclosures made in this litigation. Rather, the opinions disclosed in the Expert Report are based

on facts and analysis conducted by Smith & Nephew's expert, as set forth in detail in the Expert Report. *Ex. B* to Hologic's Motion (Dkt. # 77). The contentions served by Smith & Nephew in this litigation merely disclosed those theories to Hologic as part of discovery in this matter.

Second, the August 31<sup>st</sup> Order required Smith & Nephew to file "infringement contentions based on the claims of the patent as construed by the court, not on configurations of the accused device." Dkt. # 63. The August 31<sup>st</sup> Order was not a substantive adjudication of Smith & Nephew's infringement theories, nor did it restrict Smith & Nephew to a single theory of infringement. Rather, it specified that Smith & Nephew's contentions must be based on the "claims of the patent as construed by the court."

As a preliminary matter, neither of the terms that are the subject Hologic's instant motion (*i.e.*, "drive member" and "cutting member") have specifically been construed by this Court.<sup>2</sup> Further, as detailed in Smith & Nephew's briefs in opposition to Hologic's other pending motion to "strike," Smith & Nephew's Amended Contentions contentions, as well as Smith & Nephew's theories of infringement as set forth therein and in the Expert Report, comply with the August 31<sup>st</sup> Order. Dkt. # 71 at p. 10-15 (discussing, in particular, the "drive member" claim element at issue in the instant motion to "strike"); Dkt. #75 at p. 2-4 (also discussing Smith & Nephew's construction of "drive member," including its consistency with this court's claim construction). Smith & Nephew incorporates by reference those detailed arguments in its prior and pending briefs (Dkt. ## 71 and 75) on precisely this topic, as though fully set forth herein, and will not burden the court with a full reiteration of those arguments. Thus, while the Expert Report is not

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<sup>2</sup> As noted in Smith & Nephew's briefing in opposition to Hologic's other pending motion to strike, this Court construed the claim element "drive member attached to the cutting member" as a result of the Parties' dispute over the meaning of the term "attached." However, prior to the present dispute (including the dispute raised in briefing regarding Smith & Nephew's June 2<sup>nd</sup> contentions), the parties had not raised a dispute over the meaning of the individual terms "cutting member" or "drive member."

“based” on Smith & Nephew’s contentions (whether in June 2<sup>nd</sup> or September 9<sup>th</sup> form), the application of the term “drive member” to the Accused Device as set forth in the opinions disclosed in the Expert Report is entirely consistent with the Court’s existing claim construction, and, therefore, with the August 31<sup>st</sup> Order.

Hologic’s continued representations to the contrary are little more than mischaracterizations of Smith & Nephew’s theory, and nowhere is this clearer than the figures Hologic submits at page 2 of its motion. Dkt. #77 at p. 2. Hologic again claims that Smith & Nephew’s infringement theory presents the court and, if necessary, jury with “a multiple-choice test involving three, mutually inconsistent infringement options.” *Id.* As described in detail in Smith & Nephew’s Opposition to Hologic’s motion to “strike” the contentions, and as also described in the Expert Report, Smith & Nephew’s theory does no such thing. Rather, Smith & Nephew argues that the claimed “drive member” is not limited to a single, non-movable component within the claimed drive. *See* Dkt. #71 at pp. 5, 10-15. Smith & Nephew then argues that, under a theory of infringement pursuant to the doctrine of equivalents, the Accused Device meets the claim element “drive member attached to the cutting member” *regardless* of what components of the drive of the Accused Device make up the claimed “drive member” or “cutting member” because of the insubstantial differences between that patented claim element and the Accused Device. *Id.*; Expert Report, *Ex. B* to Hologic’s Motion, Dkt. #77 at, *e.g.*, p. 20-24. Smith & Nephew also argues that the Accused Device literally meets the claim element “drive member attached to the cutting member” if the drive member of the Accused Device is composed of specific components. Expert Report, *Ex. B* to Hologic’s Motion, Dkt. #77 at, *e.g.*, p. 20.

The static illustrations included in the Expert Report, and selectively cut out on page 2 of Hologic's motion (Dkt. #77), are intended to illustrate Dr. Hogan's opinion with respect to infringement of the Accused Device, whether literal or under the doctrine of equivalents. However, they do not (and never have) represent the "multiple choice" that Hologic suggests. Rather, Smith & Nephew's theories remain securely housed in the well-known doctrines of literal infringement and infringement under the doctrine of equivalents. That Hologic disagrees with those theories is a matter of fact that Hologic is entitled to present in opposition to Smith & Nephew's theories. However, there is absolutely *no* basis for Hologic's request to restrict Smith & Nephew's ability to present both theories to the court, and, if necessary, to the jury.

Finally, Hologic suggests in a footnote that the Expert Report "does not follow the amended contentions that S&N filed in response to the Court's August 31, 2011 order. (*See* Doc. No. 64 (no mention of multiple theories)." Dkt. #77 at p. 3, n. 1. Again, Hologic has it wrong. With respect to the claim element "drive member attached to the cutting member," the amended contentions disclose both Smith & Nephew's literal infringement theory, and its infringement theory under doctrine of equivalents, specifying that the "drive member" of the Accused Device consists of at least one component of the drive of the Accused Device, and the "cutting member" of the Accused Device consists of at least another component of the drive of the Accused Device. Amended Contentions, Dkt. # 64 at, *e.g.*, p. 4-5. As described above, in the Expert Report itself, and at length in Smith & Nephew's briefing in opposition to Hologic's other pending motion to strike (Dkt. ##71 and 75), this disclosure is *not* inconsistent with the opinions disclosed in the Expert Report.

**III. HOLOGIC’S ATTEMPTED REACH IS GROSSLY OVERBROAD, INsofar AS THE CLAIM TERM “CUTTING MEMBER” APPEARS IN CLAIM ELEMENTS THAT HOLOGIC HAS HERETOFORE *NEVER CONTESTED*.**

The sheer scope of Hologic’s request for relief in its motion belies its real intention – to avoid summary adjudication on the merits of Smith & Nephew’s infringement claims. Not content to request relief as to infringement theories that it actually disputes, Hologic now seeks to preclude expert testimony “relating to the ‘*cutting member*’ and ‘drive member’ limitations *found in all asserted claims*.” Dkt. #77 at p. 1 (emphasis added). What Hologic fails to mention is that the claim term “cutting member” appears in more than just the claim element that has been the subject of contention in its prior briefing, *i.e.*, a “drive member attached to the cutting member.” For example, the claim term “cutting member” also appears in the claim element “a cutting member including an implement for cutting tissue,” which is an element of *all* independent claims asserted in this case (1, 27, 28 and 32); “cutting member” also appears in the claim element “an outer tubular member, the cutting member being received within the outer tubular member,” which is an element of independent claim 32 asserted in this case. *See e.g.*, Amended Contentions, Dkt. #64 at 4-13. Thus, Hologic’s requested relief now encompasses, for the first time, *all asserted claims in this matter*, since they all have claim elements other than a “drive member attached to the cutting member” that also include the term “cutting member.”

However, *Hologic has asserted no non-infringement position with respect to either of these additional claim elements*. *See e.g.*, Hologic’s Final Non-Infringement Contentions, Ex. A to Dkt. #66 at p. 1 (identifying no infringement contention with respect to claim element 1b, “a cutting member including an implement for cutting tissue”); p. 13 (with respect to claim element 32.4, citing to the infringement contentions set forth for elements 14 and 15, neither of which address an infringement contention as to the “cutting member” element). Despite the fact that



Hologic does not even dispute whether the Accused Device meets many of those claim elements, it still seeks to preclude expert testimony on them.

Hologic should not be permitted to pull the wool over the collective eyes of Smith & Nephew and this court any longer. Smith & Nephew's infringement contentions and the opinions of its expert are supported by the record, comply with the orders of this court and Federal rules of evidence and procedure, and are consistent with Smith & Nephew's contentions. Hologic can present its non-infringement defenses during summary judgment and at trial, but it is not entitled to decide how Smith & Nephew should be presenting its own case.

WHEREFORE, S&N respectfully requests that this Court:

(a) deny Hologic's Motion to Strike Portions of Smith & Nephew's Expert Report on Damages;

(b) deny Hologic's request to vacate the Scheduling Order until the resolution of Hologic's motion;

(c) to the extent that the Scheduling Order is not vacated, extend the remaining deadlines for expert reports and discovery on issues of liability as follows:

(i) Parties' rebuttal reports on issues of validity and non-infringement to be served on **November 14, 2011**;

(ii) Hologic's sur-rebuttal report on issues of secondary considerations to be served on **November 21, 2011**;

(iii) Expert depositions on issues of invalidity/validity and infringement/non-infringement to be completed by **December 9, 2011**;

(d) grant Smith & Nephew its costs and fees incurred in preparing and arguing this Opposition; and

(e) grant such other and further relief as justice may require.

**REQUEST FOR ORAL ARGUMENT**

Pursuant to Local Rule 7.1 (D), S&N respectfully requests oral argument of Hologic's Motion, as it believes that oral argument may assist the Court.

Date: October 28, 2011

/s/ Joshua S. Barlow

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**CERTIFICATE OF SERVICE**

I, Joshua S. Barlow, do hereby certify that a true copy of the above document was filed through the Court's ECF system on this 28th day of October, 2011 and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Joshua S. Barlow

Joshua S. Barlow